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
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PLEASE DIRECT CORRESPONDENCE TO OUR WARRENTON OFFICE

FACSIMILE TRANSMISSION COVER SHEET

DATE: December 23, 2005

TO: Office of Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450RE: U.S. Patent Application No. 10/776,970
For: REAGENT SET AND METHOD FOR DETECTING CHOLESTEROL
IN A HIGH DENSITY LIPOPROTEIN OR LOW DENSITY
LIPOPROTEIN [AS AMENDED]
Our Ref: 3190-011-01FROM: Luke A. Kilyk, Esq. 

FAC. TEL. NO.: 1-571-273-8300

NUMBER OF PAGES (INCLUDING THIS COVER SHEET): 5

Items Attached: Petition to Direct Examiner to Withdraw Finality
Rejection and to Examine Claims on the Merits -- 4 pagesI hereby certify that this correspondence is being facsimile transmitted to the United States Patent and
Trademark Office, Fax No. 1-571-273-8300 on December 23, 2005.Kim Blum
Name of Person Signing Certificate
Signature

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Kim Blum
Name (Print)


Signature

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | | |
|-----------------------|-------------------|---|-------------------|------------------|
| In re Application of: | KISHI et al. |) | Examiner: | Ralph J. Gitomer |
| | |) | | |
| Application No.: | 10/776,970 |) | Group Art Unit: | 1655 |
| | |) | | |
| Filed: | February 11, 2004 |) | Confirmation No.: | 3712 |
| | |) | | |
| Docket No.: | 3190-011-01 |) | Customer No.: | 33432 |

For: REAGENT SET AND METHOD FOR DETECTING CHOLESTEROL IN A HIGH DENSITY LIPOPROTEIN OR LOW DENSITY LIPOPROTEIN [AS AMENDED]

PETITION TO DIRECT EXAMINER TO WITHDRAW FINALITY OF FINAL REJECTION AND TO EXAMINE CLAIMS ON THE MERITS

Office of Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

December 23, 2005

Sir:

The Applicants petition the United States Patent and Trademark Office to direct the Examiner to withdraw the finality of the rejection of the Office Action of October 24, 2005 in the above-identified application and to direct the Examiner to provide an Office Action on the merits of the pending claims.

This petition should be granted in view of the following information.

(1) A final Office Action was issued in the above-identified application on October 24, 2005. The Office Action did not include any action on pending claims 14 - 35 on the merits, but rather alleged that claims 14 - 33 were directed to an invention that is independent or distinct from the invention originally claimed. (Method claims 34 and 35 were treated as withdrawn claims on account of their dependency from claims 14 and 22, respectively.) The Examiner

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Petition dated December 28, 2005
Response to Office Action of October 24, 2005

alleged that the applicant had received an action on the merits for the originally presented invention and that the invention had therefore been constructively elected by the original presentation for prosecution on the merits. The Examiner then treated all of the pending claims as being withdrawn from consideration under 37 C.F.R. 1.142(b) and M.P.E.P. §821.03. The Examiner's position that claims 14 - 33 are directed to an invention that is independent or distinct from the invention originally claimed is clearly in error, as discussed herein.

(2) Claims 14 - 35 were added to the application in a Preliminary Amendment dated February 11, 2004.

Representative claim 14 read as follows:

14. A reagent kit for detecting a cholesterol in a high-density lipoprotein, comprising a first reagent and a second reagent, wherein said first reagent comprises an ion strength increasing compound and a nonionic surfactant, and said second reagent comprises a first enzyme reacting the cholesterol in the high-density lipoprotein and a second enzyme comprising cholesterol dehydrogenase or cholesterol oxidase, or both.

In a non-final Office Action dated July 6, 2005, claims 14 - 35 were rejected. The Office Action included a rejection of claims 14 - 35 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleged that the claims are directed to a kit or a method of employing a kit, but that the specification as originally filed does not disclose a kit.

In a timely filed Amendment dated September 26, 2005, the Applicants argued that the claims were sufficiently described to meet the written description requirement with respect to the term "kit." In particular, Applicants pointed out to the Examiner that the specification described sets or groups of the reagents, such as the first reagent and the second reagent. To make the

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support for the claimed invention more evident, the preamble of claims 14 - 33 was changed from reagent "kit" to reagent "set." It should have been clear to the Examiner that this amendment was not an election of a invention distinct and different from what was already elected, but was merely a change in claim phraseology to highlight the support for the claimed invention in the specification. In particular, except for amendments that were made to address the art rejections in the Office Action, no changes were made to the body of the claims. Nevertheless, in the final Office Action of October 24, 2005, the Examiner alleged that a "reagent set" is a distinct invention from a "reagent kit" and treated all of the pending claims as being withdrawn from consideration. The Office Action did not address the pending claims on the merits. The Examiner maintained the position that the reagent set is different from a reagent kit in a telephone discussion on October 26, 2005 with Attorney Ralph Webb, and refused to consider the claims on their merits.

(3) It is the Applicants' position that there is no essential difference between a reagent kit and a reagent set and that the terms may be used synonymously and interchangeably. The Examiner has provided no evidence or support whatsoever for his position that the terms refer to distinct inventions. Even if there were instances where persons skilled in the art have used the terms to refer to different inventions, there is clearly no difference in the present set of claims, since the body of the claims directed to a reagent set and the body of the claims directed to a reagent kit are identical. There is no structure or ingredient in the set of claims directed to a reagent kit that is not found in the set of claims directed to a reagent set, and vice versa. Therefore, the position taken by the Examiner that claims 14 - 33 presented in Applicants' amendment dated September 26, 2005 are a different invention from claims 14 - 33 as they appear in the Preliminary Amendment dated February 11, 2004 is completely without merit.

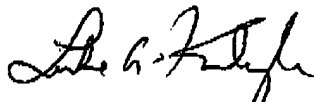
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(4) In view of the above facts, the United States Patent and Trademark Office is respectfully requested to direct the Examiner to withdraw the finality of the Office Action of October 24, 2005 and to provide an Office Action on the merits of pending claims 13 - 35.

Any decision on this Petition should be sent by facsimile to the undersigned at the facsimile number below.

If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



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